

News digest 8 Q4, 2005

Dear partners, friends, and colleagues,

The following is a summary of recent, current, and upcoming activities at the Meningitis Vaccine Project (MVP). We welcome your comments and suggestions at <u>info@meningvax.org</u> and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

If you wish not to receive this update, simply reply to this email, changing the subject to "unsubscribe MVP news digest."

Vaccine Development Activities

• Serum Institute of India Limited prepared four lots of meningococcal A conjugate (MenA conjugate) vaccine. These lots will be used for Phase II clinical trials and stability studies.

Clinical Activities

- Phase I week 4 safety and immunogenicity data are in and validated for the 74 Indian volunteers. The database lock was done at the end of 2005, and statistical analysis is underway. Preliminary results will be available by the end of January.
- A site visit was conducted to the Center for Vaccine Development (CVD) in Mali, one of the study sites selected for the first Phase II pivotal study scheduled to start in 2006. The MVP team met with National Health Authorities representatives, including Expanded Programme on Immunization managers, to apprise them of the upcoming study and ask for their collaboration. Professor Ogobara Doumbo participated in the meetings and field visits as a Project Advisory Group (PAG) representative member. He provided strong advice regarding all study aspects, particularly in terms of community approach, in light of his in-depth scientific and practical experience conducting clinical trials in Mali.
- As part of site capacity-building, investigators from CVD and MVP team members visited the Niakhar Project in Senegal. The Niakhar site belongs to the INDEPTH network (*An International Network of field sites with continuous Demographic Evaluation of Populations and Their Health in developing countries*) and has been producing high-quality longitudinal, population-based health data since the 1960s. The purpose of the visit was to reinforce CVD capacities in conducting longitudinal follow-up studies of the populations who will participate in the MenA conjugate vaccine trials. Both sites learned about each other's methods and tools, and this first visit will serve as a basis for future collaborations between trial sites.
- The MVP clinical team drafted a serology plan that will be further refined with all collaborators in light of Phase I results.
- In collaboration with Afferenz (the Life Sciences Division of Megasoft Consultants, Inc.) and iGATE Clinical Research International, MVP has instituted a pilot study of electronic data capture (eDC) software. eDC is a system that eliminates paper in the data collection process by capturing the data directly into custom-designed electronic databases.

Surveillance Activities

• The World Health Organization (WHO) Multi-Disease Surveillance Center (MDSC) team based in Ouagadougou, Burkina Faso, organized a training workshop for the implementation

of enhanced meningitis surveillance in nine northern states of Nigeria. The workshop was held in Nigeria on October 25–29.

• The MDSC team held a training for district laboratory personnel in northern Benin on November 7–12.

Epidemiological Research

- A full report of the Informal Consultation on Meningococcal Carriage Studies in Africa convened in Geneva on September 23 is available on the WHO Initiative for Vaccine Research web site (<u>http://www.who.int/vaccine_research/diseases/soa_bacterial/en/index2.html</u>). Plans to take this initiative forward are underway.
- MVP and partners gave several presentations at the November 26–29 international conference, *Challenges in the African Meningitis Belt, from Genomics to Surveillance, Control and Prevention Strategies.* The conference took place in Niamey, Niger, and was organized by Institut Pasteur, Paris, France, and the Centre d'Étude et de Recherche pour les Méningocoques et les Schistosomiases (CERMES), Niamey, in partnership with the Fondation Mérieux, Lyon, France.

Vaccine Introduction Strategy and Communication

- A vaccine introduction strategic plan for the MenA conjugate vaccine was developed at a workshop in Ouagadougou from December 4–14, 2005. The document will be distributed to partners for review before being shared with PAG members in March 2006.
- MVP continues its series of interviews with PAG members. After featuring Professor Francis Nkrumah and Dr. Aissatou Touré-Baldé, MVP introduces Professor Ogobara Doumbo, director of the Malaria Research and Training Center at the University of Bamako, Mali. Professor Ogobara was initiated to the "art and ethics of healing" by his grandfather, a traditional healer in the Malian dogon country. To find out how the 8-year-old boy grew to become an expert in tropical medicine, parasitology, and ethics, and to read what he has to say about the PAG, MVP, and bringing a new meningococcal vaccine to Africa, click on this link: http://www.meningvax.org/files/PAG-interviews-Prof-O-Doumbo-May2005.pdf.

Recent Hires

Five new staff recently joined MVP: Ms. Florence Baudry, administrative assistant, January 2006; Mrs. Rose Faju, secretary to WHO focal point, November 2005; Dr. Elisa Marchetti, clinical operations manager, January 2006; Mr. Lionel Martellet, clinical assistant, December 2005; and Ms. Davegnee Servoz, administrative assistant, October 2005. For a short biography of Florence, Rose, Elisa, Lionel, or Davegnee, please visit http://www.meningvax.org/team.htm#major.

Au Revoir and Thank You

• In December 2005 Dr. Carl Frasch, a strong supporter and codeveloper with Dr. Robert Lee Che-Hung of the conjugation technology for the MVP MenA conjugate vaccine, retired from the Center for Biologics Evaluation and Research of the Food and Drug Administration (CBER/FDA). Dr. Willie Vann will take over as new head of carbohydrate vaccines at CBER/FDA; Dr. Lee continues his work at CBER/FDA. On December 16, 2005, Marc LaForce participated at a ceremony honoring Dr. Frasch at the National Institutes of Health campus. The MVP team would like to express its deepest appreciation to Dr. Frasch for his work to improve African public health through the development of conjugate meningococcal vaccines.

That's all for now from the MVP team. Stay tuned for our next news digest (April 2006). We look forward to receiving your comments at <u>info@meningvax.org</u>.

Created in 2001, the Meningitis Vaccine Project is a partnership between WHO and PATH. The mission of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

For more information on MVP, please visit our website at http://www.meningvax.org.